Supreme Court, U.S.
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No. 99-991120

IN THE
Supreme Court of the United States

BALDEV RAJ BHUTANI, NEELAM BHUTANI,
and ALRA LABORATORIES, INC.

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Seventh Circuit

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PETITION FOR WRIT OF CERTIORARI

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January 3, 2000

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QUESTIONS PRESENTED

1. Whether this Court should exercise its supervisory power when the Seventh Circuit reversed the trial judge's ruling granting Defendants a new trial for Brady violations without reviewing the trial judge's findings of fact that stability data in FDA's files was suppressed, was favorable to the defense, and undermined confidence in the jury's verdicts?

2. Whether, if it had actually reviewed the district court's factual findings, the Seventh Circuit could have found that the judge who presided over a ten-week trial was "clearly erroneous" in holding that there was a "reasonable possibility" that the suppressed evidence might have made a difference, where "[i]t seemed to the [district] court at the time [of trial] that the verdict could have gone either way . . .?"

3. Whether the government's mischaracterization of its trial arguments misled the Seventh Circuit?

LIST OF PARTIES

Plaintiff is the United States of America.

Defendants/Petitioners are Baldev Raj Bhutani, Neelam Bhutani, and ALRA Laboratories, Inc.

ALRA Laboratories, Inc. does not have any parent companies or subsidiaries.

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Defendants Baldev Raj Bhutani, Neelam Bhutani, and Alra Laboratories, Inc. respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Seventh Circuit in this case.

OPINIONS BELOW

On December 17, 1997, the Honorable John F. Grady, United States District Judge for the Northern District of Illinois, issued a 30-page, unpublished Memorandum Opinion and Order granting the Motion of Defendants for a New Trial Based on Newly Discovered Evidence and/or Violations of Brady v. Maryland, reprinted in the appendix hereto ("App.") at 16a. The United States Court of Appeals for the Seventh Circuit issued an opinion reversing the district court and remanding for reinstatement of convictions and sentencing, reported at 175 F.3d 572, and reprinted at App. 1a. The Seventh Circuit later denied Plaintiffs' Petition for Rehearing and Suggestion for Rehearing En Banc, reprinted at App. 49a.

JURISDICTION

The Seventh Circuit entered its order reversing the district court on April 28, 1999, and denied Defendants' Petition for Rehearing and Suggestion for Rehearing En Banc on October 4, 1999. 28 U.S.C. § 1254(1) confers jurisdiction on this Court.

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED IN THE CASE

The Fifth Amendment to the United States Constitution provides, in relevant part, "No person . . .shall . . . be deprived of life, liberty, or property, without due process of law . . . ." "[S]uppression by the prosecution of evidence favorable to an accused upon request violates due process where the evidence

is material either to guilt or to punishment . . . ." Brady v. Maryland, 373 U.S. 83 (1963).

STATEMENT OF THE CASE

After a ten-week trial, the jury convicted Dr. Baldev Raj Bhutani, his wife Neelam Bhutani, and Alra Laboratories, Incorporated ("Alra") of conspiracy and various violations of the Federal Food, Drug and Cosmetic Act ("FD&C Act"). The Bhutanis own and run Alra, a generic drug manufacturer.

The lead allegations in the Indictment, which were the primary focus at trial, related to Alra's manufacture of lots 52-230-P and 52-231-P of Lactulose Syrup, USP. Lactulose Syrup is a prescription laxative, produced in liquid form, that treats liver disease by removing ammonia that builds up in the colon. Tr. 1575, 1691-97.

Alra first mixed the bulk solutions for lots 52-230 and 52-231 in June, 1986, and bottled the lots. After getting approval to market Lactulose Syrup from the Food and Drug Administration ("FDA") in July, 1988, Alra's Quality Control laboratory tested samples from both lots. Each lot assayed at 100% of label claim for the active ingredient, and the pH values for the two lots ranged from 5.3 - 5.6, well within the approved pH range for Lactulose Syrup of 3.0 - 7.0. Lab tests for related substances, which are measurements of saccharides that would be present if the active ingredient was breaking down, were also well within limits. Joint Appendix below ("J.A.") at 377, 398.

The Government contended that a week after Alra obtained these passing lab results, Defendants nonetheless believed that the lots were "degraded" and "decomposed," and that to mask that decomposition, seven Alra employees unpacked both lots from storage crates, opened each of approximately 3,300 bottles

from the two lots, added sodium hydroxide (an ingredient in Alra's FDA-approved formulation) bottle-by-bottle with some sort of turkey baster or syringe, shook the bottles, recapped the bottles, labeled them, and repacked them in crates. The Government alleged that this process violated the FD&C Act because Alra's approved manufacturing process required that sodium hydroxide be added in a mixing vat during the initial manufacture of Lactulose Syrup. The Government also charged that Alra created false batch records because the employees failed to document the alleged addition of sodium hydroxide. J.A. 65-66, 69-70. The defense acknowledged that seven employees had unpacked the bottles, replaced some leaking caps, labeled the bottles, and repacked them, but the defense denied that additional sodium hydroxide had been added as alleged in the Indictment.

At a trial eight years afterward, four of the seven employees involved in the repacking testified for the government. The government witnesses admitted that they did not know what had been added to the bottles. Tr. 1260, 3224, 3248. One government witness said that they did not syringe every bottle, another said she was not sure they syringed every bottle. Tr. 1530, 3257. The other three employees testified for the defense, and did not remember a syringe being used to add something to lots 52-230 and 52-231. Tr. 4377-4411; 4412-36; 4623-47. The defense argued that the government witnesses were remembering a process where under- or over-filled bottles or bottles with leaking caps were emptied and refilled with a syringe. One of the government witnesses said that it was possible that something was being taken out of the bottles, instead of being put in. Tr. 1530. As the district court noted, "[t]he description of the injection process given by the various employees who allegedly did it seemed unlikely in the extreme, unless there was some compelling motive for the defendants to have required them to engage in such a procedure. Not all of

the employees who would have known about the incident agreed that it had occurred. Both of the Bhutanis denied that it had occurred. It seemed to the court at the time that the verdict could have gone either way . . . ." District court Memorandum Opinion ("Memo Op."), App. 45a. The Government's theory of motive was thus crucial to its case.

The Government's Theory Of Motive

The Government spelled out its theory of motive in the Indictment. Counts Three and Six alleged that lots 52-230 and 52-231 were adulterated because they "consisted in part of a decomposed substance, namely decomposed lactulose raw material." J.A. 65, 69. As the district court's opinion so ably summarized, Government counsel argued that the lots were

> old and had become unstable or dangerously close to being unstable, so that they were either medically ineffective or close to becoming medically ineffective. It was for this reason, according to the government, that defendants injected these aged Lactulose lots with Sodium Hydroxide, a base, in order to raise the pH of the Lactulose and make it appear safe for use. . . . The motive was profit, said the government.

Memo Op., App. 18a.

The difficulty with this allegation was that there was never any proof that the lots were decomposed or degraded; nine years after manufacture retained samples for the lots assayed at over 100 percent of label claim for the active ingredient, although the pH had declined to approximately 2.9. Tr. 5550-51. So the Government built its case by repeatedly arguing that a decline in pH meant that the lots had "decomposed" or

"degraded." In her opening statement, Government counsel argued:

> The defendants instructed their employees to open up the bottles of Lactulose, those 1986 bottles, and inject a chemical called sodium hydroxide into the bottles in order to raise the pH and make it appear that the product had not, in fact, degraded. They added this undocumented component through an unapproved procedure to mask or to hide the underlying degradation of the product. . . .
>
> You will first hear from Dr. Kevin Hicks, and he is the carbohydrate chemist. He is an expert on Lactulose, and he will tell you that Lactulose is a type of carbohydrate called a disaccharide, and this disaccharide degrades over time. And as time passes, the product breaks down into its component parts. **And you can detect this degradation of the product by testing its pH. And as the product degrades, the pH will decrease.** . . .
>
> In addition, another expert, Dr. John Senior, the gastroenterologist, will tell you . . . that if a product is sufficiently old and the disaccharide has degraded into its component products, the Lactulose simply will not work. The drug will be ineffective in treating the patient's advanced liver disease.

Memo Op., App. 21a-23a (emphasis added).[1]

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[1] The Government's Reply Brief in the Seventh Circuit contained the following amazing sentence: "The government did not dispute that before being spiked with sodium hydroxide the old Lactulose lots were within the approved pH range, medically effective, and stable." Reply

The Government called expert witness Dr. Kevin B. Hicks, a carbohydrate chemist who invented a process for manufacturing Lactulose and has published more scientific articles on Lactulose than anyone in the United States. Tr. 1560, 1565. Government counsel asked Dr. Hicks six separate times on direct whether a decrease in pH for Lactulose meant that the product had degraded. Each time the answer was yes. Tr. 1582, 1587-88 (twice), 1589, 1597, 1598. Government counsel twice asked Dr. Hicks whether the addition of sodium hydroxide would mask degradation of the product. Tr. 1588, 1600-01. Government counsel also elicited an unquantified statement from Dr. Hicks that degradation of Lactulose would eventually increase in a "cascading or a snowballing type of an effect." Tr. 1580.

The Government called Dr. John Senior, a gastroenterologist. As the district court stated at a post-trial hearing on September 11, 1996:

> [o]ne of the most impressive witnesses at the trial, if not the most impressive witness, was the Government's expert, Dr. Senior. On page 27 of the transcript of his testimony, he is asked, I believe, by [Government counsel]: "Question: if Lactulose is degraded into monosaccharide components, would it work to treat portal systemic encephalopathy. Answer: No, it won't work if it is degraded or split because the split products of Lactulose are fructose and galactose which are easily absorbed sugars. They are gone. They never get to the colon." And he goes on in more detail on the following page, to talk about how if the Lactulose is degraded, it

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Brief of Appellant at 6. As the quote above demonstrates, the Government argued that the lots were medically ineffective and unstable throughout the trial.

> won't be medically effective. Then he is asked at line 17 of page 28: "Question: And would a physician be able to ascertain what was wrong if Lactulose had broken down into disaccharide forms?" Now, there would be absolutely no purpose in asking that question, it seems to me, unless the Government was contending that the question was relevant to the fact situation before the jury. The question addresses a situation where Lactulose had broken down into its [monosaccharide] form. And Dr. Senior, in what was, in my distinct recollection, an absolutely devastating answer said the following: "That makes it very hard on the physician because a lot is going on in these sick patients. They have got a failing liver. They often have. They are now getting failure of the brain function. They often have kidney failures that goes with the liver failures. They have got a lot of problems, and the last thing a physician is going to think of when he prescribes a drug is that it isn't what it is supposed to be." . . .
>
> Small wonder that the Court has a serious concern that, due to the tactics of the Government, the jury gained the impression that this Lactulose was dangerous to any patient who used it.

Motions hearing, 9/11/96 at 10-11 (emphasis added).

The Conflict In Expert Testimony

The defense called Dr. John F. Robyt, a professor of Biochemistry at Iowa State University, as an expert witness. Tr. 4256. Dr. Robyt testified that the chemical bond holding Lactulose together was very strong, and that it was a very stable product. Tr. 4256. Dr. Robyt testified that the pH would have to drop below 1.0 before Lactulose would begin to degrade

significantly. Tr. 4270. Dr. Robyt explained that a decline in pH from 6.0 to 3.0 would not result in any significant degradation of the active ingredient. Tr. 4276-77, 4340-42. Dr. Robyt denied that Lactulose would degrade in a cascading effect at a pH of 3.0. Tr. 4278-80.

Government counsel attacked Dr. Robyt's qualifications, pointing out that his scientific articles and research had not dealt specifically with Lactulose. Tr. 4261-62. Government counsel cross-examined Dr. Robyt at length, suggesting in unquantified terms that a decrease in pH meant that Lactulose was degrading.

The Government Told The Jury
That The Lactulose Was "Degraded"

In closing argument, Government counsel repeated the argument that a decline in pH meant that the Lactulose had degraded, and that the "degraded" Lactulose sold by the Defendants may have killed patients:

> Now, after you heard about all the chemistry, you heard from a physician, and that was Dr. John Senior. **And he told you the medical consequences of this degradation and why in very human terms this all matters**. . . .
>
> But as Dr. Senior pointed out, the Lactulose has to reach the large intestine in order for it to work. If the Lactulose is already broken down, **if it is already degraded** into its monosaccharide form, the monosaccharides will be absorbed in the small intestine, they'll be digested and the Lactulose in its disaccharide form will never reach the colon, the site of the effective treatment. And it will be rendered ineffective in treating

> patients with hepatic coma or portal systemic encephalopathy.

Memo Op., App. 25a-26a (first closing)(emphases added).

Both Government counsel also argued that the motive for adding sodium hydroxide to lots 52-230 and 52-231 was to mask the "degradation" of those lots:

> They did this to make sure that if anyone tested the pH of the drug product, it would test high. They wouldn't know it was old, they wouldn't know it had degraded. They did this so the consumers couldn't know of the truth about the products that they were buying. They wouldn't know the pH had dropped, they couldn't tell the product had degraded, and they wouldn't suspect that it had passed the expiration date.

Tr. 5585 (first closing).

> They raised the sodium hydroxide, so if three months or six months down the road AARP or -- I forgot the other company they sold this to -- Bioline I think it was, checked the pH, it would appear that this stuff was new. It didn't just have to be within spec, it had to be new because this stuff was labeled with a September of 1989 expiration date.

Tr. 5805 (rebuttal closing).

The Jury Returned Guilty Verdicts

After a ten-week trial, the jury credited the testimony of key government witnesses who testified that some substance was added to every bottle in lots 52-230 and 52-231, and returned

verdicts against Defendants on multiple felony counts supported by the testimony of those witnesses. To return its verdicts, the jury had to reject the testimony of Dr. Robyt, the defense expert who contradicted the government's scientific theories about Lactulose. The jury also had to reject the testimony of several other defense witnesses, including the Bhutanis, who testified that Alra did not add sodium hydroxide to lots 52-230 and 52-231 as alleged. The district court noted, "All counts of conviction were entwined with the government's profit motive theory and its contention that the Defendants would cut any corners they had to regardless of the consequences to public health. A finding that the Defendants were so motivated could well have provided the basis for the jury's verdict on the other charges, each of which was vigorously contested." Memo Op., App. 47a.

Post-Trial Discovery Showed No Correlation Between A Decline in pH And Medical Effectiveness

In May, 1996, three months after the jury's verdict, the United States Pharmacopeia ("USP") proposed a downward revision of the acceptable pH range for Lactulose, from 3.0 - 7.0 to 2.5 - 6.5. The USP based its proposal on data submitted by UDL, another manufacturer of Lactulose. The USP proposal stated:

> [b]ased on information received that stability data has shown a downward trend in pH over time, it is proposed to revise the pH range in this monograph. The proposed pH change is reported not to have any significant impact on the safety and quality of this product: it does not in any way affect the laxative properties of the product, and it does not affect the level of the related substances.

J.A. 284-85.

The defense filed a Motion for a New Trial Based on Newly Discovered Evidence And/Or Violation of Brady v. Maryland, arguing that the data cited by the USP was in the possession of FDA before the trial and undercut the Government's theory that a decline in pH correlated to a decline in medical effectiveness. J.A. 269-85. The defense followed up with a motion for discovery, requesting the stability data from other manufacturers of Lactulose in FDA's files. J.A. 292. The district court ordered discovery over the Government's opposition. J.A. 301.

The data from other manufacturers that was in FDA's files before trial showed that there was no correlation between a decline in pH and the potency of the product; showed that Lactulose was stable as a rock, plateauing at over 90% of label claim for years after manufacture even as pH declined to 3.0 and below; and showed that there was no "cascading" effect or accelerated degradation of the product at pH values of 3 or below. See Memorandum in Support of Post-Trial Motion, filed May 12, 1997; J.A. 343-51. Discovery revealed that on August 15, 1994, UDL had submitted its stability data to FDA showing no correlation between a decline in pH and the potency of the product, and had asked FDA to revise the pH range downward. A year later the Government argued a scientific theory to the jury directly contrary to the UDL data.

Data in FDA's files before the trial exposed the Government's theory of motive as fiction. Government counsel had argued that Alra wanted to increase the pH of the Lactulose lots to "make sure that if anyone tested the pH of the drug product, it would test high. They wouldn't know it was old, they wouldn't know it had degraded." Tr. 5585. Alra was the first generic manufacturer of Lactulose approved by the FDA. And lots 52-230 and 52-231 were among the first five lots that Alra released. The other three lots that Alra released at roughly the same time had pH values ranging between 4.9 and 5.85 at

the time of release. Alra's customers thus would not have known anything about the age of lots 52-230 and 52-231 from comparing their pH values to other Alra lots.

Post-trial Brady discovery revealed that Merrill Dow, the name brand manufacturer that had monopolized the market for Lactulose in the U.S. for years, generally released product with initial pH values between 4.0 and 5.0. According to the Government's theory that a higher pH value would indicate a "newer" product, any sophisticated customers familiar with Lactulose would have believed that any product with a pH above 4.5 was "new." There was thus no motive at all for Alra to increase the pH of its lots.

The Government did not call any Alra customers at trial to testify that they would have believed that a product with a pH of 4.6 was "old." In light of the revelation that the innovator routinely released product with pH values between 4.0 - 5.0, defense counsel doubt that the government even asked any Alra customers whether they would have recognized the "age" of any batches based on pH values well within specifications. It appears that the Government constructed this theory based on speculation, without ever checking the contrary evidence in FDA's files.

The Trial Judge Found That Stability Data In FDA's Files Was Material, And Granted A New Trial

The district court requested extensive briefing from the parties summarizing the stability data that had been in FDA's possession before trial, and on the government's use of the word "degradation" during trial. Finally, in a 30-page Memorandum Opinion that quoted extensively from the government's arguments to the jury and its questions to expert witnesses, the district court found that the government had

suppressed the stability data in FDA's files, that the data was favorable to the defense, and that the data was material. Explicitly finding that the stability data in FDA's files "seriously undermines the court's confidence in the verdicts," the district court granted Defendants' motion for a new trial. App. 16a-48a.

The government appealed. On appeal, the National Pharmaceutical Alliance "(NPA"), a national trade association representing more than 160 generic pharmaceutical manufacturers, distributors, and related firms, was granted leave to file a brief amicus curiae. The NPA was concerned about the government's argument that the prosecution team had no obligation to search FDA's files for exculpatory materials in an FD&C Act prosecution. The NPA argued that because of the FDA's "special place in our health care system:"

> [i]t is absolutely necessary that the FDA be obligated to take enforcement action only when–as an agency–it can assure the Court that its position is fully supported by the data and information in its files. To suggest that it may proceed in a civil or criminal matter without conducting a thorough review of its own files is absolutely contrary to the responsibility that Congress has placed on the agency.

Brief Amicus Curiae of the National Pharmaceutical Alliance in Support of Affirmance, at 2.

The Government's Misleading Arguments On Appeal

In addition to arguing that it had no obligation to search FDA's files for Brady material, the government told the Seventh Circuit that it "did not dispute that before being spiked with sodium hydroxide, [lots 52-230 and 52-231] were within the pH

range, medically effective, and stable." Government's Reply Brief at 6. **The government's statement** that it conceded all along that the lots were medically effective and stable **is utterly, demonstrably false**. Counts 3 and 6 of the Indictment alleged that the lots were adulterated because they consisted of a "decomposed substance, namely decomposed lactulose raw material." Government counsel argued for conviction on those counts to the jury. Government counsel asked their Lactulose expert, Dr. Kevin Hicks, the following questions: "As lactulose degrades, does the pH change? . . . Would the lowering of the pH o[f] the lactulose solution be indicative of degradation? . . . When lactulose is used as a pharmaceutical product is the expiration date reflective at all of the degradation process? . . . Would the addition of sodium hydroxide mask the degradation of the product if you were testing the pH? . . . Is the pH measure a measure–one possible measure of the stability of a lactulose product? . . . What would the decrease in pH indicate relating to stability?. . . Would the addition of sodium hydroxide mask any degradation; that is, make it unable to discern degradation?" Tr. 1582, 1587-89, 1597-1598, 1600-01. If the government conceded all along that the Lactulose lots were medically effective and stable, why would government counsel ask those questions? If the government agreed with defense expert Dr. John Robyt that there is no correlation between a decline in pH and a decline in medical effectiveness of Lactulose, why did government counsel attack Dr. Robyt's opinion and question his expertise on Lactulose? Tr. 4261-62.

On January 24, 1996, during oral argument on Defendants' Rule 29 motion, government counsel told the district court that "[t]he easiest indicator of deterioration is the reduction in the pH . . . ." Tr. 1/24/96 at 125. Government counsel told the district court that "the sodium hydroxide addition . . . would mask the degradation." Tr. 1/24/96 at 126. Government counsel told the district court, "what Dr. Hicks testified to that

the product was decomposing–the testimony of Dr. Hicks was that that was evidence that the drop in pH was evidence of the decomposition, and that, with regard to the expiration date, the government's theory as was added to mask that." Tr. 1/24/96 at 148. Government counsel told the Court, "as Dr. Hicks testified, the product will degrade over time, and after 18 months the product would have degraded to such a point that it would not longer be appropriate for use as a medicine . . . ." Tr. 1/24/96 at 149 (emphasis added). The Court specifically asked government counsel during the Rule 29 argument whether the government was contending that the product would become decomposed after the alleged addition of sodium hydroxide and after the product was shipped. Government counsel responded, "No, your Honor. As of August 12th, 1988, when they were packaging this product for resale, we had a product that had been manufactured in, I believe it was either December of 1985 or January of 1986. That is when the raw material had been manufactured; that that material, according to the testimony of Dr. Hicks, would begin to decompose as of its time of manufacture and it's either December of '85 or January of '86; that the expiration date based on the testing that had been done and the literature was that Lactulose by 18 months after its manufacture would be decomposed to the degree that it could no longer be used as a medicine." Tr. 1/24/96 at 150 (emphasis added).

In its April 22, 1996 submission to the Probation Officer for Mrs. Bhutani, the government wrote: "If the lactulose degrades and fails to reach the colon in its original form, it is rendered ineffective . . . . The degradation of the product is evidenced by a decrease in the pH. . . ." April 22, 1996 letter to Ms. Elisa J. Ehrlich, at 7 (emphasis added).

As the quotes above indicate, the government argued throughout the trial that there was a correlation between a

decline in pH (even a decline within the allowable range for pH) and the degradation, or medical ineffectiveness, of Lactulose Syrup. The Defendants contended throughout the trial that there was no correlation between a decline in pH and a decline in medical effectiveness, and that they therefore had no motive to increase the pH of the lots. The stability data in FDA's files demonstrated conclusively that Defendants were right.

The Seventh Circuit Adopted The Government's Mischaracterization That "The Government Did Not Argue That The Lactulose Was Unfit"

The Seventh Circuit swallowed the government's argument hook, line, and sinker: "after reviewing the trial transcript, we do not agree that the government's argument was premised on the fact that ALRA spiked the Lactulose lots because they would soon be unfit for use. In fact, the government did not argue that the Lactulose was unfit, or close to unfit." 175 F.3d at 578, App. 11a. How could the Seventh Circuit say that, when the Indictment alleged that Defendants added sodium hydroxide to a "decomposed substance, namely decomposed lactulose raw material," and when government counsel argued to the jury:

> This case is about a corporation and its two officers' repeated decisions . . . to line their own pockets instead of ensuring that their customers were receiving safe and effective medicine and to put their private profit over the public health. . . . They injected a chemical into the product to mask the fact that the product had degraded. Why? Because destroying the product would cost money, and selling the expired product would make money.

Memo Op., App. 19a, 22a, quoting government counsel's opening argument.

Think about how different that argument would have been if government counsel had told the jury, "They injected a chemical into lots that were 'within the approved pH range, medically effective, and stable.'" Government's Reply Brief at 6. If the jury had heard an argument like that, would it have found that the Defendants acted with intent to defraud?[2]

The Seventh Circuit Did Not Review The District Court's Findings That The Stability Data Was Material

The Seventh Circuit not only mischaracterized the government's arguments at trial, it also mischaracterized the basis of Defendants' motion for a new trial, and the district court's opinion. The Seventh Circuit made a fact determination that "[t]he real evidence that the defendants rely on in their motion is the eventual publication of the U.S.P.'s proposal to lower the effective [pH] range of Lactulose." 175 F.3d at 577, App. 9a. It is hard to understand how the panel could have made that fact determination, because the district court specifically wrote that he did not rely on the United States Pharmacopoeia ("U.S.P.") proposal. Having created a straw man, the panel then knocked it down, holding that because the

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[2] To the extent that the Seventh Circuit relied on the government's theory that ALRA had placed "inaccurate expiration date[s]" on the Lactulose lots, the Government's first witness, Dr. Eric Duffy, a Ph.D review chemist employed by FDA, conceded that one of several reasonable interpretations of Dr. Bhutani's correspondence with the FDA was that Alra was allowed to sell "old" lots of Lactulose it had on hand based on passing final lab testing of the product. Tr. 333-35. The jury acquitted defendants on counts 2 and 5, which alleged that the Lactulose lots had been labeled with inaccurate expiration dates.

U.S.P. did not publish the proposal until after the trial, "the evidence in question was not within the possession of the government," there was thus no Brady violation as a matter of law, and "we need not decide whether it was exculpatory or material." 175 F.3d at 577, App. 49a.

The district court's opinion granting defendants a new trial did not rely on the U.S.P. proposal:

> There is some sleight of hand in the government's position. The primary favorable evidence is not the U.S.P. recommendation made in June of 1996, four months after the trial. . . . [T]he fact that the recommendation had not been made prior to the trial is irrelevant to the present motion. The favorable evidence that was suppressed is the stability data that was in the possession of the government for years prior to trial, which it does not deny it knew about and which it did not disclose to the defense.

Mem Op., App. 39a (emphasis added).

The Seventh Circuit's opinion misapprehended numerous other facts. The opinion said that "[o]ne way of testing the stability of Lactulose is to measure its pH level." 175 F.3d at 575, App. 3a. The stability data in FDA's files showed that pH was not a reliable way to test the stability of Lactulose, because the product remained potent and effective even after the pH dropped. The Seventh Circuit said that "[i]f the pH level becomes too low, the drug will no longer be effective to fight the liver disease." Id. Post-trial discovery of stability data in FDA's files showed that Lactulose was stable as a rock, and that there was no correlation between a decline in pH and the potency or medical effectiveness of the drug.

The Seventh Circuit said that the government presented evidence that the pH on lots 52-230 and 52-231 had risen between February, 1998, and August, 1998. The Seventh Circuit said that the evidence of increasing pH values tended to prove that defendants had added sodium hydroxide to the Lactulose lots, and that "[i]t was agreed by both government and defense expert witnesses that there is no naturally occurring process which will increase the pH level of Lactulose over time." 175 F.3d at 575, App. 4a. The Seventh Circuit thus ignored another crucial part of the district court's opinion:

> There is another respect in which the stability data [in FDA's files] is material, quite aside from the question of motive. The evidence at trial was that testing of the lots in question had shown the pH level of the Lactulose to have increased for no apparent reason after the date of the alleged injections. The government's expert witness, Dr. Hicks, testified that the only explanation for this occurring in a closed container would be the addition of a base, such as sodium hydroxide. The defense expert, Dr. John Robyt, disagreed and said that the variations could be due to laboratory error. The government relied heavily on the testimony of Dr. Hicks in its final argument to the jury.
>
> The competitors' stability data shows some variation in pH - going up, back down and then up again - that are arguably similar to those shown in the ALRA records for the lots in question. The government argues that the increases in pH shown in the competitors' stability data are significantly lesser increases than those shown in the ALRA test data. Whether this is true or not is a somewhat complicated factual question, and one properly for the jury. [footnote by the district court: In its effort to distinguish the competitors' data, the

> government offers considerable factual information and analysis that is found neither in the data itself nor in the trial record.] But even if it were true, it detracts little, if at all, from the materiality of the competitors' test data. Dr. Hicks testified that no increase could occur in a closed container without tampering. If the competitors' data show that any increases occurred in their laboratories, the data appears to contradict Dr. Hicks on this important question. Had the competitors' data been available to the jury, the defendants would have had support for their position that any unexplained variation in their own test results could have been due to laboratory error.

Memo Op., App. 44a-45a.

The Seventh Circuit said that the jury found that Defendants had added sodium hydroxide to the lots by returning convictions on count 4, and the Seventh Circuit seemed to conclude that the convictions on count 4 somehow weakened the district court's ruling with respect to counts 3 and 6. 175 F.3d at 579, App. 13a. As the district court said in another context in his opinion: "[t]his is another question-begging argument; it assumes the defendants did inject the Lactulose. We are concerned on this motion with the suppression of evidence that went to the question of whether they did so." Memo Op., App. 44a.

The Seventh Circuit opinion summarized testimony from government witnesses that Alra had added sodium hydroxide to Lactulose lots 52-230 and 52-231 in an assembly line fashion, and concluded "[t]he fact that the U.S.P. proposed a lower effective pH range for Lactulose is of no consequence to the case since the government never argued that the Lactulose's pH was outside of the effective range, or even close to being outside the range." 175 F.3d at 579, App. 12a. The district

court judge, who presided over the ten-week trial, strongly disagreed:

> the government repeatedly emphasized that the naturally occurring process of degradation was continuous, so that even if the actual pH level was at 4.6 when the injections occurred, the jury still could have concluded that the defendants recognized the need for a "booster" before distribution to avoid detection of a real problem that would appear shortly after distribution. Had the jury known [about the stability data in FDA's files], the jury could well have reached a different conclusion as to whether the defendants had a motive to jiggle the pH of the product.

Memo Op., App. 42a-43a.

REASONS FOR GRANTING THE WRIT

An experienced district court judge who presided over a ten-week trial made specific findings of fact that stability data in FDA's files was suppressed by the government, was favorable to the defense, and was material because it seriously undermined confidence in the jury's verdicts. Instead of reviewing the district court's findings under a "deferential" or "clearly erroneous standard," the Seventh Circuit made its own inaccurate fact determination that "[t]he real evidence that the defendants rely on in their motion is the eventual publication of the U.S.P.'s proposal to lower the effective range of Lactulose." 175 F.3d at 577, App. 9a. And as a result of demonstrably inaccurate government arguments that "[t]he government did not dispute that before being spiked with sodium hydroxide the old Lactulose lots were within the approved pH range, medically effective, and stable," the Seventh Circuit ignored the district court's factual finding, based on careful quotations from

the trial record, that "[t]he government's contention at trial was that defendants' Lactulose lots in question were old and had become unstable or dangerously close to being unstable, so that they were either medically ineffective or close to becoming medically ineffective." Memo Op., App. 18a.

The combination of inaccurate government arguments and a failure by the Seventh Circuit to address the district court's finding that stability data in FDA's files was Brady material resulted in an opinion that "so far departed from the accepted and usual course of judicial proceedings . . . as to call for an exercise of this Court's supervisory power." S. Ct. Rule 10.

In addition, the Seventh Circuit's opinion conflicts with the Ninth Circuit's opinion in United States v. Wood, 57 F.3d 733 (9th Cir. 1995), which reversed the district court's denial of a Brady motion based on exculpatory information in FDA's files.

I. THE SEVENTH CIRCUIT NEVER REVIEWED THE DISTRICT COURT'S FINDINGS OF FACT THAT STABILITY DATA IN FDA'S FILES WAS SUPPRESSED, WAS FAVORABLE TO THE DEFENSE, AND UNDERMINED CONFIDENCE IN THE JURY'S VERDICTS.

The district court made a specific finding that:

> The primary favorable evidence is not the U.S.P. recommendation made in June of 1996, four months after the trial. . . . [T]he fact that the recommendation had not been made prior to the trial is irrelevant to the present motion. The favorable evidence that was suppressed is the stability data that was in the possession of the government for years prior to trial, which it does

> not deny it knew about and which it did not disclose to the defense.

Mem Op., App. 39a (emphasis added).

As a reviewing court, the Seventh Circuit had an obligation to consider the district court's findings. "Factual findings of a district court are, of course, entitled to substantial deference and will be reversed only for clear error." United States v. Taylor, 487 U.S. 326, 337 (1988), citing Anderson v. Bessemer City, 470 U.S. 564 (1985).

Instead of reviewing the district court's findings, the Seventh Circuit substituted its own judgment and made a fact determination that "[t]he real evidence that the defendants rely on in their motion is the eventual publication of the U.S.P.'s proposal to lower the effective [pH] range of Lactulose." 175 F.3d at 577, App. 9a. The Seventh Circuit then held that because the U.S.P. did not publish the proposal until after the trial, "the evidence in question was not within the possession of the government," there was thus no Brady violation as a matter of law, and "we need not decide whether it was exculpatory or material." 175 F.3d at 577, App. 9a.

The Seventh Circuit's mistaken belief about the "real evidence that the defendants rely on" prevented the Seventh Circuit from considering the "real evidence" that the district court relied on–"the stability data that was in the possession of the government for years prior to trial, which it does not deny it knew about and which it did not disclose to the defense." The district court made factual determinations that the stability data "undermined confidence in the jury's verdicts." The Seventh Circuit could only overturn those factual determinations by finding that they were "clearly erroneous." The Seventh Circuit never made such a finding, because it never considered the

evidence that supported the district court's decision. Cf. Parker v. Dugger, 498 U.S. 308, 321 (1990)(where Florida Supreme Court failed to reweigh non-statutory mitigating factors based on mistaken conclusion that trial court had not found any non-statutory mitigating factors, "there is a sense in which the court did not review Parker's sentence at all.").

The prosecution team was clearly responsible for the data in FDA's files. As this Court recently held, "the individual prosecutor has a duty to learn of any favorable evidence known to the others acting on the government's behalf in this case, including the police." Strickler v. Greene, ___ U.S. ___, 119 S.Ct. 1936, 1948 (1999), quoting Kyles v. Whitley, 514 U.S. 419, 437 (1995). And in United States v. Wood, 57 F.3d 733 (9th Cir. 1995), the Ninth Circuit reversed the district court's denial of a Brady motion based on exculpatory information in FDA's files. To the extent, if any, that the Seventh Circuit's statement "[w]e disagree that the evidence in question was in the possession of the prosecution" applies to the stability data that the district court relied upon, the Seventh Circuit's holding here conflicts with this Court's precedents and the Ninth Circuit's holding in United States v. Wood.

II. THE STANDARD FOR REVERSING A TRIAL JUDGE'S FACTUAL DETERMINATION THAT SUPPRESSED EVIDENCE WAS "MATERIAL"IS VERY HIGH, AND THE SEVENTH CIRCUIT NEVER ADDRESSED THAT STANDARD.

The district court made factual determinations that the stability data in FDA's files was favorable to the defense and "material" under Brady standards. Because it did not address the stability data in FDA's files, the Seventh Circuit never reviewed those district court findings. To reverse, the Seventh Circuit would have had to hurdle the "clearly erroneous"

standard, which is extraordinarily high in the Brady context. That is because "[t]he question is not whether the defendant would more likely than not have received a different verdict with the evidence, but whether in its absence he received a fair trial, understood as a trial resulting in a verdict worthy of confidence." Kyles v. Whitley, 514 U.S. 419, 434 (1995). Further, "materiality . . . is not a sufficiency of evidence test. A defendant need not demonstrate that after discounting the inculpatory evidence in light of the undisclosed evidence, there would not have been enough left to convict." Kyles v. Whitley, 514 U.S. at 434-35.

Accordingly, the district court did not have to find by even a preponderance of the evidence that the result would have been different. To reverse, the Seventh Circuit would have had to find that the judge who presided over a ten-week trial was "clearly erroneous" in believing that there was a "reasonable possibility," but less than a 50% probability, that the suppressed evidence might have made a difference, where "[i]t seemed to the court at the time [of trial] that the verdict could have gone either way . . . ." Memo Op., App. 45a. On this record, such a finding would be unjust, because the district court's "firsthand appraisal of the record was thorough and entirely reasonable . . . ." United States v. Agurs, 427 U.S. 97, 114 (1976). This Court's recent opinion in Strickler v. Greene, ___ U.S. ___, 119 S.Ct. 1936 (1999) is not to the contrary. In Strickler the district court had granted a new trial based on a cold habeas record. Here the district court sat through a ten-week trial, and believed that the verdict could have gone either way even before post-trial discovery revealed the government's scientific theories to be unfounded.

The Seventh Circuit's failure to address the district court's factual findings reflects an inconsistent approach to Brady violations within the Seventh Circuit's own cases. In United

States v. Boyd, 55 F.3rd 239, 242 (7th Cir. 1995), the Seventh Circuit upheld the district court's grant of a new trial based on suppressed impeachment evidence, and wrote:

> Judge Aspen had for months on end listened to witnesses--had heard, had not merely read, their testimony, and had watched them as they gave it. And he had observed the jurors as they listened to the witnesses. A trial judge of long experience, he would have developed a feel for the impact of the witnesses on the jury--and how that impact might have been different had the government played by the rules--that an appellate court, confined to reading the transcript, cannot duplicate. Judge Aspen may have been mistaken; we might suspect that he was mistaken; but unless we are convinced he was mistaken, we have no warrant to reverse. That is what it means to say that appellate review is deferential.

III. THE GOVERNMENT'S MIS-CHARACTERIZATION OF ITS TRIAL ARGUMENTS MISLED THE SEVENTH CIRCUIT.

The government argued to the Seventh Circuit that it never disputed that the Lactulose lots were "within the approved pH range, medically effective, and stable." Government's Reply Brief. The Seventh Circuit fell for the government's reverse of field, writing that "after reviewing the trial transcript, we do not agree that the government's argument was premised on the fact that ALRA spiked the Lactulose lots because they would soon be unfit for use. In fact, the government did not argue that the Lactulose was unfit, or close to unfit." 175 F.3d at 578, App. 11a.

Somehow, **the government convinced the Seventh Circuit that when it used the word "degraded," it meant "old, but medically effective and stable, and not close to unfit."** The government's brief and the Seventh Circuit's opinion stand common sense and the English language on their heads. An experienced trial judge who sat through a ten-week trial concluded "[t]he government's contention at trial was that defendants' Lactulose lots in question were old and had become unstable or dangerously close to being unstable, so that they were either medically ineffective." Memo Op., App. 18a. He backed up his conclusion with pages of quotations from the government's arguments to the jury, the government's questions to its expert witnesses, and the government's submissions to probation after trial. Memo Op., App. 18a-29a.

The government's arguments to the Seventh Circuit were "clearly erroneous." The district judge was right, and the quotations from his opinion prove it. The following quotations graphically illustrate the government's change of position:

Government's Reply Brief at p. 9:

> The terms "degraded" and "decomposed" were never used at trial by the government to argue or suggest that before the drug was spiked in 1988 it was dangerously close to being medically ineffective.

Government's position during trial:

> Dr. John Senior, the gastroenterologist, will tell you that . . . if a product is sufficiently old and the disaccharide has degraded into its component products, the Lactulose

simply will not work. The drug will be ineffective in treating the patient's advanced liver disease.[3] . . .

Q. Would Lactulose, if it had degraded into its component parts, be effective in treating portal systemic encephalopathy?

A. No, it would not.[4] . . .

[Dr. Senior] told you the medical consequences of this degradation and why in very human terms, this all matters. . . . If the Lactulose is already broken down, if it is already degraded into its monosaccharide form, the monosaccharides will be absorbed in the small intestine, they'll be digested, and the Lactulose in its disaccharide form will never reach the colon, the site of the therapeutic treatment. And it will be rendered ineffective in treating patients with hepatic coma or portal systemic encephalopathy.[5]

Government's Reply Brief at 12:

The therapeutic effectiveness of Lactulose is not dependent on its pH, and the government never contended otherwise.

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[3] Memo Op. App. 23a, quoting government counsel's opening statement.

[4] Memo Op., App. 24a, quoting testimony of Dr. John Senior.

[5] Memo Op., App. 25a-26a, quoting government counsel's closing argument.

Government's position during trial:

And as time passes, the product breaks down into its component parts. And you can detect this degradation of the product by testing its pH. And as the product degrades, the pH will decrease.[6]

Government's Reply Brief at 6:

The government did not dispute that before being spiked with sodium hydroxide the old Lactulose lots were within the pH range, medically effective, and stable.

Government's position during trial:

This case is about a corporation and its two officers' repeated decisions . . . to line their own pockets instead of ensuring that their customers were receiving safe and effective medicine and to put their private profit over the public health. . . . They injected a chemical into the product to mask the fact that the product had degraded. Why? Because destroying the product would cost money, and selling the expired product would make money.[7]

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[6] Memo Op., App. 22a, quoting government counsel's opening argument.

[7] Memo Op., App. 19a,22a, quoting government counsel's opening argument.

CONCLUSION

The petition for a writ of certiorari should be granted.

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